Urogenital TEM-PCR™ Panels

TEM-PCR™ (Target Enriched Multiplex-Polymerase Chain Reaction) is a unique amplification strategy designed to overcome the barriers that prevent true multiplex PCR.

This powerful technology can discern the presence of multiple organisms in an accurate, confirmatory, and timely manner.

TEM-PCR™ Advantages

- Can be run from urine or swab specimens
- Identifies difficult to culture pathogens
- Investigates for multiple pathogens simultaneously
- Differentiates pathogens that present with similar symptoms
- Uses specimen adequacy control to eliminate false negatives

Test Name	Test Code	CPT* Codes	Components
Health Panel (15:1)	906142	87481 x5; 87798 x5; 87491; 87511; 87529 x2; 87591	Atopobium vaginae, Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Chlamydia trachomatis, Gardnerella vaginalis, Herpes Simplex Virus Types 1 & 2, Mycoplasma hominis, Mycoplasma genitalium, Neisseria gonorrhoeae, Trichomonas vaginalis, Ureaplasma urealyticum
Bacterial Vaginosis Panel (5)	906452	87798 x4; 87511	Ureaplasma urealyticum, Atopobium vaginae, Gardnerella vaginalis, Mycoplasma hominis, Mycoplasma genitalium
Candidiasis Panel (5)	906450	87481 x5	Candida albicans, Candida glabrata, Candia krusei, Candida parapsilosis, Candida tropicalis
Sexually Transmitted Disease Panel (STD5)	906451	87491; 87591; 87661; 87529 x2	HSV 1&2, Neisseria gonorrhoeae, Trichomonas vaginalis, Chlamydia Trachomatis

Testing is available for both female and male patients.

*The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

Sonora Quest Laboratories™

A Subsidiary of Laboratory Sciences of Arizona

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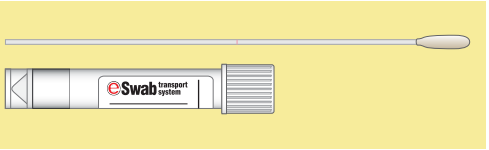
Collection Instructions

White-Cap e-Swab - Routine Culture Swab (Supply #25784)



The swab or urine specimen for Urogenital TEM-PCR™ testing must be collected using a White-Cap e-Swab containing a vaginal/urethral/endocervical swab, a transfer pipette for urine specimens and a white top transport tube. Urogenital TEM-PCR™ testing can be performed on: urine, vaginal swabs, or endocervical swabs. Please ensure that the sample submitted to the laboratory is labeled with two patient identifiers (patient name, date of birth, etc.).

Endocervical Swab:

1. Use the White-Cap e-Swab.
2. Remove the endocervical swab from the packaging being careful not to contaminate the swab by touching it to any surface.
3. Insert the flocked tip of the specimen swab into the endocervical canal.
4. Gently turn the swab and allow it to absorb the secretions of the endocervix.
5. Withdraw the swab carefully to avoid contamination.
6. Without contaminating the swab, place the swab into the White-Cap e-Swab transport tube all the way to the bottom and rotate the swab 5 or more times in the solution to elute any diagnostic material from the flocked swab. Break the swab at the scored line on the shaft and discard the swab after eluting the diagnostic material into the transport medium in the tube.
7. Recap the transport tube carefully to ensure that the cap seals tightly.

Vaginal Swab:

1. Use the White-Cap e-Swab.
2. Remove the swab from the packaging being careful not to contaminate the swab by touching it to any surface.
3. Insert the tip of the specimen swab about two inches (5 cm) into the opening of the vagina.
4. Gently rotate the swab for 5 to 10 seconds against the sides of the vagina to ensure adequate sampling. Secretions from the vaginal vault may also contain diagnostic material that is representative of the infectious process (the same swab can be used to collect these secretions). Gently rotate the swab for 15 seconds to ensure adequate sampling.
5. Withdraw the swab carefully.
6. Handle the cap and tube carefully to avoid contamination.
7. Without contaminating the swab, place it into the White-Cap e-Swab transport tube all the way to the bottom and rotate it 5 or more times in the solution to elute any diagnostic material from the flocked swab. Break the swab at the scored line on the shaft and discard the swab after eluting the diagnostic material into the transport medium in the tube.
8. Recap the transport tube carefully. Ensure that the cap seals tightly.

Urethral Swab: (MALE OR FEMALE)

1. The healthcare provider uses sterile cotton or gauze to clean (gently wipe) the opening of the distal urethra.
2. Using the White-Cap e-Swab transport tube, gently insert the swab about ¾ inch into the urethra and turn to capture exudate and dislodge urethral cells that may harbor intracellular organisms.
3. Remove the swab from the urethra and place it into the White-Cap e-Swab transport tube, rotate the swab 5 or more times in the solution to elute any diagnostic material from the flocked swab. Break the swab at the scored line on the shaft and you may discard the swab after eluting the diagnostic material into the transport medium in the tube.

Urine Specimen: (STD)

Female

1. Using a sterile, plastic, preservative-free collection container, collect the voided urine specimen by allowing the urine to flow over the external genitalia during the collection. Do not overfill the collection container.
2. Open the White-Cap e-Swab and discard the collection swab.
3. Unscrew the White-Cap e-Swab transport tube taking care not to spill the transport buffer. Handle the cap and tube carefully to avoid contamination. Withdraw the swab carefully to avoid contamination.
4. Use the plastic transfer pipette to transfer 1 mL of urine from the collection cup into the transport buffer. Half of the transfer pipette volume may be required to transfer the necessary volume of urine specimen (it should not exceed the volume of the buffer already in the tube). Recap the transport tube carefully to ensure that the cap seals tightly.

Male

1. Using a sterile, plastic, preservative-free collection container, collect the initial 5-10 mL segment of the first morning void. If the first morning void cannot be obtained, collect a 5-10 mL voided specimen at least one hour from the previous void.
2. Open the White-Cap e-Swab and discard the collection swab.
3. Unscrew the White-Cap e-Swab transport tube taking care not to spill the transport buffer. Handle the cap and tube carefully to avoid contamination.
4. Use the plastic transfer pipette to transfer 1 mL of urine from the collection cup into the transport buffer. Half of the transfer pipette volume may be required to transfer the necessary volume of urine specimen (it should not exceed the volume of the buffer already in the tube).

Note: Because certain organisms are intracellular, there must be enough human cells present to detect the organism. Diatherix tests the specimen for human DNA to ensure that an adequate number of cells are present for a valid result.